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EXAMINER	
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ART UNIT	PAPER NUMBER
1637	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/507,521	BERTHIER ET AL.	
	Examiner	Art Unit	
	Cynthia B. Wilder, Ph.D.	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 July 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment filed 7/9/2007 is acknowledged and has been entered. Claims 1, 4-10, 14-18 have been amended. Claims 1-19 are pending. All of the arguments have been thoroughly reviewed and considered but are not found persuasive for the reasons that follow. Any rejection not reiterated in this action has been withdrawn as being obviated by the amendment of the claims.

This action is made FINAL.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Previous Rejections

3. The claim rejection under 35 USC 112 second paragraph is withdrawn in part. The prior art rejections under 35 USC 102(b) are maintained and discussed below. The prior art rejection under 102(e) is withdrawn in view of Applicant's arguments.

Claim Rejections - 35 USC § 112

4. Once again, claim 1 and 4 are vague and confusing at the recitation "selectively fixing" because the specification does not provide a limiting definition as to what is meant by "selectively fixing" and it cannot be determined Applicant's intent. Clarification is required.

Response to Arguments

5. Applicant traverses the rejection on the following ground: Applicant states that the term is widely used in the field of extraction and the present situation, means that the interface layer retains the macromolecule or the agglomerate from the liquid sample without retaining other molecules. Applicant requests the rejection be withdrawn.

This argument is not found persuasive because the term has not been defined in the instant specification and it cannot be determine how the monolayer is able to selectively fix a macromolecule. Clarification is required.

Claim Rejections - 35 USC § 102

6. Once again, claims 1, 2, 4, 6, 9, 15 and 19 are rejected under 35 USC 102(b) as being anticipated by Unger (WO 01/64164 A2, September 2001). Regarding claim 1, Unger teaches a method comprising forming a stabilized dispersion of an emulsion type from a medium comprising said liquid sample and an interface layer, which interface is before forming the stabilized dispersion, a monolayer located the surface of the liquid sample and which is able to selectively fix said macromolecules to be concentrated and reforming said interface layer by the resorption of the dispersion formed during said forming a stabilized dispersion, said macromolecule or said agglomerate being concentrated in said interface layer; and (page 4, line 26 to page 5, line 22; page 13, line 25 to page 14, line 8 and page 34, line 23 to page 35, line 16).

Regarding claim 2, Unger teaches wherein said forming a stabilized dispersion is carried out by mechanical agitation of the medium comprising the liquid sample and said interface layer (page 34, line 23 to page 35, line 1, which teaches probe sonication).

Regarding claim 4, Unger teaches wherein the interface layer comprises at least one molecule which selectively fixing said macromolecules (page 34, line 23 to page 35, line 16).

Regarding claim 6, Unger teaches wherein the macromolecules is selected from the group consisting of nucleic acids, proteins and antigens (page 12, lines 1-4 and page 13, lines 11-17).

Regarding claim 9, Unger teaches wherein the macromolecule is DNA (page 13, line 15).

Regarding claim 15, Unger teaches a method for the detection of a macromolecule comprising concentrating within a layer, said macromolecule according to claim 1 and detecting said macromolecule (see examples).

Regarding claim 19, Unger teaches wherein said molecule is a surfactant molecule (page 15, lines 4-28). Therefore, Unger meets the limitations of the claims noted above.

Response to Arguments

7. Applicant traverses the rejection by stating that Unger neither discloses nor suggests an interface layer located at the surface of the liquid sample and being able to fix selectively the compound to be concentrated contained in the liquid sample, nor does Unger disclose or suggest the formation of a dispersion from a medium comprising the liquid sample and the interface layer, nor reforming the interface layer by resorption of the stabilized dispersion. Applicant states Unger also does not teach or suggest a monolayer located at the surface of the liquid as the interface layer.

These arguments are not found persuasive. In response to Applicant's arguments, the examiner maintains that Unger does teach the limitations of the claims as currently written. Unger teaches forming a monolayer located on the surface of a liquid sample which is the interface layer that comprises the macromolecule to be concentrated within the nanocapsules (see page 22). Unger specifically mentions the formation of an interface at page 22, and further implies the formation of an interface with the addition of an oil (page 19) being added to the solution to form an immiscible solvent and formation of a stabilized dispersion (see entire reference, especially the example 1). In regards to Applicant's arguments concerning the reforming steps, it is noted that the instant application does not provide any limiting definition for the "reforming" or "resorption" of the dispersion as claimed in the reforming step. Further, the specification does not even describe or disclose how the claimed reforming step is performed. Thus, examiner has interpreted the reforming step as simply additional steps wherein the stabilized dispersion is subjected to further analysis which allows the macromolecules to be concentrated or analyzed. Unger meets this limitation by teaching that after stabilization, the stabilized surfactant micelle is transferred from the stabilizing apparatus to a second aqueous composition in the presence of a solute which is capable of extracting the biocompatible polymer component and further allows formation of the nanocapsule comprising the targeted macromolecule(s) (see for example, page 5). Applicant's arguments are not sufficient to overcome the prior art rejection. Accordingly, this rejection is maintained.

8. Once again, Claims 1-2, 4-6, 9, 10, 14, 15 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Jaschke et al {Jaschke, herein} (Nucleic acids research, vol. 22, No. 10, pages 1880-1884).

Regarding claim 1, Jaschke teaches a method comprising forming a stabilized dispersion of an emulsion type from a medium comprising said liquid sample and an interface layer, said interface layer capable of fixing macromolecules and reforming said interface layer by the resorption of the dispersion formed during said forming a stabilized dispersion (page 1880-1881, section entitled "MATERIALS AND METHODS"; and figure 1).

Regarding claim 2, Jaschke teaches wherein said forming a stabilized dispersion is carried out by mechanical agitation of the medium comprising the liquid sample and said interface layer (page 1881, col. 1, line 1).

Regarding claim 4, Jaschke teaches wherein the interface layer comprises at least one molecule capable of selectively fixing said macromolecules (page 1880-1881, section entitled "MATERIALS AND METHODS"; and figure 1).

Regarding claim 5, Jaschke teaches wherein the fixing of the macromolecule is by chemical affinity (pages 180-1881, section entitled "MATERIALS AND METHODS").

Regarding claim 6, Jaschke teaches wherein the macromolecules is nucleic acids (page 1880-1881, section entitled "MATERIALS AND METHODS).

Regarding claim 9, Jaschke teaches wherein the macromolecule is DNA (page 1880-1881, section entitled "MATERIALS AND METHODS").

Regarding claim 10, Jaschke teaches wherein the macromolecule is DNA and the molecule capable of fixing the DNA is functionalized with a probe to allow specific hybridization of the DNA (page 1880-1881, section entitled "MATERIALS AND METHODS").

Regarding claim 14, Jaschke teaches a method for the purification of a macromolecule, the method comprising concentrating said macromolecules within a layer using the method according to claim 1 and then eliminating the liquid sample depleted of said macromolecule (page 1880-1881, section entitled "MATERIALS AND METHODS"; note* the reference teaches wherein the layers are centrifuge and separated into separate tubes).

Regarding claim 15, Jaschke teaches a method for the detection of a macromolecule comprising concentrating within a layer, said macromolecule according to claim 1 and detecting said macromolecule (page 1880-1881, section entitled "MATERIALS AND METHODS").

Regarding claim 19, Jaschke teaches wherein said molecule is a surfactant molecule (page 1880-1881, section entitled "MATERIALS AND METHODS"; and figure 2). Therefore, meets the limitations of the claims noted above. Therefore, Jaschke meets the limitations of the claims noted above.

Response to Arguments

9. Applicant traverses the rejection on the grounds that Jashke et al does not teach or suggest the formation of dispersion from a medium comprising the liquid sample and the interface layer and reforming the interface layer by resorption of the stabilized dispersion. Applicant states that Jaschke et al do not teach a monolayer located at the surface of the liquid sample as the interface layer.

These arguments are not found persuasive. Specifically, the courts have established that during patent examination the pending claims must be interpreted as broadly as their terms reasonably allow (*In re Zletz, 893 F.2d 321-22, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989).* Contrary to Applicant's argument, Jaschke et al do teach the

limitation wherein the interface is a monolayer at the surface of the liquid sample. This limitation is expressly depicted in the Figure 1 at page 1881 which shows the interface layer at the surface of the liquid composition comprising the targeted macromolecule, said target macromolecule being concentrated in the interface layer.

In regards to Applicant's arguments concerning the reforming step, it is noted that neither the specification nor claims provide a limiting definition as to what is meant by the "reforming step" or how the step is actually performed. Given the broadest, reasonable interpretation, the examiner maintains that this limitation is taught by Jaschke et al. Jaschke et al teach wherein further analysis of the upper phase (interphase layer) is mixed with composition comprising labeled and unlabeled oligonucleotides and subjected to heating, cooling and specific incubation conditions (see page 18881).

10. Once again, claims 1, 4-6, 9-10 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Ijiro et al (cited on IDS). Regarding claim 1, Ijiro et al. teach a method comprising forming a stabilized dispersion of an emulsion type from a medium comprising said liquid sample and an interface layer, said interface layer capable of fixing macromolecules and reforming said interface layer by the resorption of the dispersion formed during said forming a stabilized dispersion (col. 2, lines 46-60; col. 3, line 35 to col. 4, line 61).

Regarding claim 4, Ijiro et al teach wherein the interface layer comprises at least one molecule capable of selectively fixing said macromolecules (col. 2, lines 46-60; col. 3, line 35 to col. 4, line 61).

Regarding claim 5, Ijiro teaches wherein the fixing of the macromolecule is by chemical affinity ((col. 2, lines 46-60; col. 3, line 35 to col. 4, line 61).

Regarding claim 6, Ijiro et al teaches wherein the macromolecules are nucleic acids (col. col. 3, lines 55-56).

Regarding claim 9, Ijiro et al teaches wherein the macromolecule is DNA (col. 3, lines 55-56).

Regarding claim 10, Ijiro et al teaches wherein the macromolecule is DNA and the molecule capable of fixing the DNA is functionalized with a probe to allow specific hybridization of the DNA (col. 3, line 54 to col. 4, line 13).

Regarding claim 15, Ijiro et al teaches a method for the detection of a macromolecule comprising concentrating within a layer, said macromolecule according to claim 1 and detecting said macromolecule (col. 4, lines 14-37). Therefore, Ijiro et al meet the limitation of the claims recited above.

Response to Arguments

11. Applicant traverses the rejection on the grounds that Ijiro et al neither discloses nor otherwise suggest forming a stabilized dispersion followed by a resorption steps.

Applicant states that both steps are fundamental in obtaining a good concentration of compounds to be extracted.

In response to applicant's arguments, that the reference does not teach a stabilized dispersion, the examiner respectfully disagree because Ijiro et al at column 4, discloses that the monolayer which is a result of the interface layer can be compressed or dispersed by controlling the surface pressure of the monolayer (lines 46-51). Thus the formation of a foam or emulsion as defined as the "stabilized dispersion" in the claim is an inherent feature of the method of Ijiro et al upon formation of the interface layer. In regards to Applicant's arguments concerning the resorption step, ijiro et al teaches further analysis is performed to determine the concentration of the target macromolecule (see examples). Applicant is again reminded that the method does not define how the resorption step is performed. Accordingly, any analysis method after forming the stabilized dispersion is broadly encompassed by the claims as currently written.

New Grounds of Rejections

THE NEW GROUNDS OF REJECTIONS WERE NECESSITATED BY APPLICANT'S AMENDMENT OF THE CLAIMS:

Claim Rejections - 35 USC § 112

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a) The claims 1-19 is confusing in the claim 1 because it is unclear how the monolayer operates to "selectively fix" the macromolecule. Additionally, it is unclear in the context of the claims how "forming a stabilized dispersion" results in concentrating the macromolecule. Likewise, the term "selectively fixes " is confusing in the claim 5 because it cannot be determine what molecule is actually require to carry out the process. A clear nexus between the claimed method steps cannot be ascertained.

Conclusion

12. No claims are allowed. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (571) 272-0791. The examiner can normally be reached on a flexible schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

cbw

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